

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN**

United States of America, *ex. rel.*

Jennifer Denk
2000 Rambling Rose Road
Waukesha, WI 53186,
Plaintiff,

Filed *In Camera* pursuant to
31 U.S.C. § 3730(b)(2).

Civil Action, File No. _____

v.

PharMerica Corporation
1901 Campus Place
Louisville KY, 40299,
Defendant.

**COMPLAINT FOR DAMAGES and INJUNCTIVE RELIEF
UNDER FALSE CLAIMS ACT**

QUI TAM ACTION FILED UNDER SEAL

Plaintiff, United States of America *ex rel.* Jennifer Denk, through her attorneys, Cross Law Firm, S.C., by Nola J. Hitchcock Cross, complains and alleges the following:

I. Parties

1. Relator, Jennifer Denk, is a citizen of the United States of America and a resident of the State of Wisconsin, residing at 2000 Rambling Rose Road in the City and County of Waukesha, State of Wisconsin 53186. At all material times Denk was and is a pharmacist licensed in the States of Wisconsin, No. 15014-040, and Alaska, No. 1810 and she was and is employed by Defendant PharMerica Corporation as a Pharmacy Operations Manager in PharMerica Corporation's Pewaukee, Wisconsin facility.

2. Relator brings this action on behalf of the United States of America pursuant to 31 U.S.C. § 3730(b)(1). The United States of America is a sovereign country whose Department of Health and Human Services pays claims submitted to it by PharMerica Corporation through its Medicaid and Medicare programs for prescription medications and other pharmaceutical products.

3. PharMerica Corporation is a Delaware corporation with its principal place of business at 1901 Campus Place in the City of Louisville, State of Kentucky 40299. PharMerica Corporation was formed as the integration of two nationwide pharmaceutical services companies: Kindred Pharmacy Services and PharMerica. PharMerica Corporation operates and manages Long Term Care Pharmacies (KPS LTC Pharmacy; PharMerica LTC Pharmacy) and Long Term Acute Care Hospital Pharmacies (KPS Hospital Pharmacy).

4. According to its website: “PharMerica Corporation maintains high standards of quality care and customer-defined services, combining cost-effective management with clinical excellence. Our technologically advanced dispensing and tracking systems ensure quality case and accurate provisions of medication.” PharMerica also states on its website: “Our mission is to lower our customers’ prescription cost while at the same time, improving the quality of patient care.”

II. Jurisdiction and Venue

5. Jurisdiction lies in this Court pursuant to 28 U.S.C. §§1331, 1345 and 31 U.S.C. §3732(a).

6. Venue is proper in the Federal District Court, Eastern District of Wisconsin *inter alia*, pursuant to 28 U.S.C. §1391(a) because a substantial part of the events or omissions giving rise to the claim occurred in this judicial district.

7. Relator previously met with the United States Drug Enforcement Administration investigators and with the Department of Justice assistant U.S. attorneys to provide information and notify them that she was intending to file this action.

III. Statement of the Action

8. This action is brought on behalf of the United States of America to recover all damages, penalties and other remedies established by and pursuant to 31 U.S.C. §§3729-3733, and on behalf of Relator Jennifer Denk to claim entitlement to a portion of any recovery obtained by the United States as a *qui tam* plaintiff authorized by 31 U.S.C. §3730.

9. Relator brings this action to impose liability upon Defendant for violations of 31 U.S.C. §3729 and non-compliance with various federal regulations by submission to the United States of certain claims for monetary reimbursement for sale of prescription drugs and other pharmaceutical products which PharMerica represents it sold to individuals entitled to payment through the United States' Medicare and Medicaid programs to the extent such claims were not eligible for such payment because they did not meet the requirements for payment due to PharMerica's non-compliance with Medicare, Medicaid, and other laws and regulations relating to the dispensing, control, sale, billing, and disbursement of pharmaceutical products, including Schedule II, III, IV and V controlled substances under the Uniform Controlled Substances Act of the States. 21 U.S.C. §812

IV. Background

PharMerica Corporation

10. In about 2007 PharMerica, Inc. and Kindred Healthcare, Inc. merged to form PharMerica Corporation. AmerisourceBergen Corporation, which was previously PharMerica's parent corporation, remains the primary provider of prescription drugs to PharMerica.

11. Defendant purchases and resells prescription drugs and other pharmaceutical products to patients in hospitals, skilled nursing facilities (“SNFs”), and assisted living facilities (“ALFs”) through contracts with those facilities. PharMerica operates approximately 95 closed retail pharmacies in approximately 41 states that serve approximately 320,000 licensed beds for patients of long-term care and other facilities. PharMerica’s closed retail pharmacies are licensed to purchase and dispense Schedule II-V controlled substances.

12. According to the February 2009 10-K report Defendant filed with the United States Securities and Exchange Commission (“SEC”) in 2008 PharMerica’s revenue derived from Medicare Part D reimbursements was \$885.8 million, its revenue derived from Medicaid reimbursements was \$181.1 million, and its revenue derived from Medicare reimbursements was \$10.1 million. Upon information and belief, approximately 90% of the individuals who receive medications from PharMerica are participants in Medicare or Medicaid and PharMerica bills the United States Government for those prescription drugs and other pharmaceutical products.

13. PharMerica employs about 6,600 employees nation-wide. Defendant directs its pharmacy operations’ compliance through its corporate Regulatory Affairs Department, Legal Department, and its corporate Human Resources Department. Defendant provides pharmacy consulting services and other services to the institutions with which it contracts and PharMerica employs “consulting pharmacists” for this purpose. According to its policies, Defendant has three management positions in each of its closed retail pharmacies: General Manager/Director of Operations, Operation/Pharmacy Manager, and Pharmacist-in-Charge, however positions go unfilled for long periods of time, requiring the remaining employees to maintain and increase the sale, billing and shipping volumes. Defendant also employs narc techs, order entry techs, fill techs, and pack techs to process its drug orders and it contracts with vendors for delivery of medications and other products to the facilities under contract with Defendant. Defendant’s

intentional lack of staffing, lack of training, lack of orientation, lack of availability of policies and procedures, productivity requirements, and general methods of operations ensure that Defendant's corporate policies and legal requirements governing the handling and dispensing of controlled substances cannot be followed regularly if at all and that claims will be presented to the United States for payment of controlled drugs which were illegally dispensed.

14. Defendant's corporate staff interviews and selects candidates for its managerial pharmacy positions throughout the United States and in so doing is aware of the lack of experience of the candidates in a closed retail pharmacy setting. Defendant requires Pharmacy Operations Managers in its facilities to sign employment contracts which require the return of \$10,000 or so if the Manager resigns within two years of starting employment, even if the resignation is in response to illegal procedures at Defendant's facilities.

15. Although Defendant has policies for processing medication orders, it does not generally make policies or procedures available regarding dispensing controlled substances. Defendant does not generally provide training or orientation to its Pharmacy Operations Managers who are charged with oversight of Defendant's staff pharmacists and Defendant's operations to dispense controlled substances. Defendant stresses productivity requirements as priorities for its pharmacy employees. Defendant does not utilize software to track its inventory of controlled substances or to track whether there are signed prescriptions for orders of controlled substances.

Defendant's Sale & Billing of Controlled Substances

16. Defendant's pharmacies receive orders for controlled substances and such orders are then entered into the computer into the AS 400 program by Order Entry Techs and the hard copies organized into corresponding batches of about 20 orders which are then assigned a batch number. A staff pharmacist (RPH-1) then verifies accuracy of the entered data and the AS 400 program assigns a prescription number and the pharmacist closes and releases the batch to

PharMerica's corporate Regional Billing Office ("RBO") in Longmont, Colorado. The AS 400 program then transfers the approved batch to "fill" status and prints labels for the medications. Fill Techs then fill the orders for prescription medications from the PharMerica inventory. The majority of the drugs are put into a Unit Dose Package, referred to as a "Bingo Card". The AS 400 prints a manifest which is matched to a batch for delivery by a private contract delivery company which makes deliveries twice daily on weekdays and once daily on weekends.

17. In Defendant's Pewaukee facility alone, about 56,000 drug orders are filled monthly, about 2,000 are filled daily of which about 12% (240) are for Schedule II-V controlled substances.

18. Defendant supplies SNFs with "narc boxes" for Schedule II substances and others for Schedule III-V substances. PharMerica maintains little control over the boxes but regularly refills them for the SNF's.

19. The PharMerica pharmacies send their drug orders to Regional Billing Offices ("RBO's") who check that the individual patient is eligible for United States government reimbursement before the orders are filled and shipped by the pharmacy. The Pewaukee, Wisconsin facility sends the order information to PharMerica's Colorado billing facility for billing to the United States Government for payment through its federally funded programs including Medicare Part A and D, CHAMPUS/TRICARE, Wisconsin Medicaid, Wisconsin Senior Care Medicaid, Illinois Medicaid, Iowa Medicaid, Indiana Medicaid, Minnesota Medicaid, Michigan Medicaid, and South Dakota Medicaid.

20. During all relevant times, the Pewaukee, Wisconsin PharMerica facility provided drugs to about 50 long-term care facilities in Wisconsin and the Michigan Upper Peninsula, about 45 of which are SNFs and the remaining are ALFs.

Relator

21. Relator Jennifer Denk commenced employment with PharMerica on or around October 30, 2008 as the Pharmacy Operations Manager ("POM") for the Pewaukee, Wisconsin PharMerica facility and she remains currently employed in that position.

22. As the POM for PharMerica in Pewaukee, Wisconsin Relator's duties include: directing and managing the pharmacy staff; communicating with SNFs and ALFs, physicians, and related personnel who are involved with the purchasing of prescription drugs and other pharmaceutical products through PharMerica; working with PharMerica management to maintain compliance with State and Federal regulations; and maintaining inventory and record keeping for controlled drugs.

23. Beginning on or around March 16, 2009 and continuing frequently thereafter, Relator began raising questions with Defendant regarding the manner in which Defendant was handling, selling, billing, and dispensing controlled substances.

24. On April 27, 2009 when Relator informed her supervisor, Melissa Maupin ("Maupin"), General Manager of the Pewaukee facility, of her concerns that PharMerica's practices of dispensing Schedule II-V controlled narcotics were not compliant with federal regulations, Maupin directed Relator to continue PharMerica's normal business practices regarding the dispensing of the narcotics without receiving prescriptions or physician signatures within seven days, despite the fact that Defendant's management at the Pewaukee facility and at the corporate level were aware that those procedures were not compliant with federal regulations.

25. On May 1, 2009 Heidi Papenthien ("Papenthien"), PharMerica's Pewaukee, Wisconsin human resources representative, directed Relator "not to worry" about the scheduled internal corporate compliance audit because they would "fix it later."

26. On May 6, 2009 Relator sent an e-mail to Maupin again expressing her concerns that PharMerica was not compliant with regulations regarding Schedule II-V controlled narcotics because prescriptions were not signed within the requisite seven days after dispensing the medication in an emergency situation, and prescriptions in non-emergency situations were being dispensed without a signed prescription at all, and no indication was made as to whether there was a basis for an “emergency dispense”. Maupin stated in response that the lack of compliance was a “global” or corporate-wide problem and that “corporate” was aware of the scope of the non-compliance. Maupin directed Relator to take no action to accomplish compliance until Corporate Director of Regulatory Compliance, Sharon Hartman (“Hartman”), came to the facility. Maupin stated that the Pewaukee facility could not make changes to procedure on its own without Corporate directives. Maupin further directed that Relator was not to make compliance changes, as they would “upset the customers”.

27. Relator called the Drug Enforcement Administration (“DEA”) on May 4, 2009. Relator spoke with Diversion Investigator Thomas B. Hill and informed him about the above compliance issues.

28. PharMerica’s corporate compliance department is and has been at all materials times well-aware of non-compliance and false billing practices in its facilities, but has taken no systematic efforts to accomplish compliance. Hartman and Dan Staffieri (“Staffieri”), a Regulatory Consultant employed by PharMerica, visited the Pewaukee, Wisconsin facility on May 11 and 12, 2009 to conduct a corporate “audit”. On information and belief, they did not “audit” anything at the facility. Relator showed Hartman and Staffieri a large number of unsigned orders for controlled substances that had been dispensed and billed to the United States substantially more than seven (7) days before. Staffieri told Relator that she should “get them cleaned up” because if the government audited them they could get \$10,000 fine for each one. Staffieri also

asked Relator to add a space to indicate “Emergency Dispense” on the AS 400-generated template to justify dispensing controlled substances without a signed prescription without regard to whether PharMerica had any information to suggest there was in fact any emergency to dispense the controlled substances.

29. PharMerica’s Director of Regulatory Compliance and its Compliance Consultant did not provide any policies or suggest any procedures to accomplish compliance; they did not direct Relator or others to cease billing the United States for claims for dispensed controlled substances which did not comply with legal and other requirements; they did not direct Relator or others to credit the United States for falsely billed claims; and they did not direct Relator or others to notify the DEA of compliance violations.

30. In mid-May 2009, Relator also told PharMerica’s corporate compliance agents that the SNF’s under contract with PharMerica were using the PharMerica provided narcotic boxes for Schedule II substances and for Schedule III-V substances like “candy jars” and that PharMerica’s lack of oversight violated legal and billing requirements. PharMerica’s practice was and is that when the boxes are returned for re-fill the procedure is to just cover the fill with a 60-day prescription on file if possible; that no pharmacist checks the re-fills; that the narcotic box usage is not reconciled; and that they are re-filled based on the usage amount. Defendant’s corporate auditor was unconcerned with the “candy jar” and lack of oversight practice and did not direct or even suggest any change in practice except to complete a DEA form if there were missing narcotics.

31. On information and belief, Defendant caused documents relating to usage of narcotics in the “narc boxes” to be shredded at least commencing in 2008 in order to eliminate any record of usage and billing.

32. In mid-June 2009, in response to the DEA visit and Relator's compliance concerns, Maupin intentionally altered computer records of narcotic drug usage, billing, and patient usage history for controlled substances dispensed and billed to the United States for certain drug orders for which there was no physician signature.

33. As a result of the said information Relator provided to the DEA, the DEA inspected the premises of PharMerica Pewaukee, Wisconsin on May 13, 2009. The DEA noticed the stack of documents on Relator's desk and investigated them. The stack contained documents of unsigned prescriptions from narcotic box prescriptions from the previous year and usage sheets that showed medications missing from the narcotic boxes. In front of Maupin, the DEA requested that Relator send all of the documents on her desk to their offices. After the DEA left, Maupin instructed Relator not to send the documents to the DEA at that time, but to "fix" the documents by "matching" them up with old prescriptions or by obtaining physician signatures. Maupin directed Relator to only send the documents to the DEA which she could "fix" and Maupin noted that the DEA had not counted the documents and they would not know if some were missing. Thereafter, Relator asked what she should tell the DEA if they ask her about compliance and Maupin repeated her said directive to Relator.

34. On June 4, 2009 Relator contacted Richard Hollar ("Hollar"), PharMerica's Corporate human resources representative, and informed him that Maupin had asked Relator to commit a felony in violation of 18 U.S.C. § 1001 by intentionally lying to the DEA by not reproducing the documents they requested, and by tampering with documents before sending them to the DEA. On June 8, 2009 after receiving no response from Hollar, Relator sent Hollar another e-mail asking to be released from her employment contract based on PharMerica's failure to comply with the regulations governing the dispensing of Schedule II controlled narcotics, and failure to assist Relator in her effort to clean-up company practices. Relator specifically stated, "I

have dedicated much time and effort into cleaning up a mess that was here long before my employment began. I have been met with resistance by other members of the lead team when trying to be compliant with state and federal laws.” Hollar informed Relator that she would have to repay the company a \$10,000 “signing bonus” if she resigned due to the non-compliance during her first two years of employment. On June 10, 2009 Hollar told Relator that he had looked into the matter and that Maupin was not asking Relator to commit a felony, but that Maupin was only “protecting the company”.

35. 21 C.F.R. §1301.71 requires that “[The pharmacy] shall provide effective controls and procedures to guard against theft and diversion of controlled substances.” Specifically, controlled substances listed in Schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet. 21 C.F.R. §1301.75. Throughout her employment with PharMerica, Relator has observed that PharMerica’s Pewaukee, Wisconsin facility does not properly secure controlled narcotic substances in its narcotics storage room. PharMerica continually violates these regulations by propping open the door to the control substance storage room and leaving the cabinets unlocked during business hours where all employees have unsupervised access to the scheduled controlled substances. PharMerica employees are not provided with any corporate policies which require securing controlled substances.

36. Every month Relator conducts an inventory of controlled substances, either personally or by delegating the duty. In a report created on May 1, 2009 for the month of April and provided to corporate, for example, Relator found missing pills for the following Schedule II narcotic medications: (a) Dextroamphetamine 10mg - 25 pills; (b) Dilaudid 1mg/ml Oral Solution - 92 pills; (c) Endocet 10/325 -193 pills; (d) Methylin 5 mg -126 pills; (e) Methylin 10 mg -816.5 pill; (f) Oxycodone 5mg -1,935 pills; (g) Oxycontin 10mg -151 pills, in addition to many other medications with missing pills or liquid amounts. PharMerica took no measures to implement

policies or procedures to control or report or otherwise follow-up on the reports of missing medications from the PharMerica inventory.

37. On numerous occasions beginning at least on November 7, 2008 PharMerica knowingly, intentionally and willfully submitted false claims, records and statements to officials of the United States for the purpose of obtaining compensation for the medications to which PharMerica was not legally entitled due to its violation of or failure to comply with legal conditions for reimbursement as follows: (1) PharMerica presented claims for payment for controlled narcotic substances based on orders that were not valid because (a) PharMerica obtained no information to support an emergency dispense and/or did not note any basis for emergency dispense, but PharMerica did dispense such controlled drugs on an emergency basis without a prescription signed by a physician; (b) the drugs were dispensed as emergency drugs in nonemergency situations without a prescription signed by a physician; (c) the drugs were properly dispensed in an emergency situation but PharMerica did not obtain or even attempt to obtain a prescription signed by a physician within the seven day timeframe or (d) no prescription was ever written for controlled drugs which PharMerica dispensed; (2) PharMerica did not credit the United States when drugs were returned unused and, in some instances, PharMerica then re-billed the United States for medications that were returned unused and previously billed to the government; (3) PharMerica billed the United States for medications allegedly administered to one patient when the medications were actually administered to other patients, including those not eligible for government payments; and (4) PharMerica billed the United States for one type of medication and then provided the patient with a different type of medication.

V. Count I. Federal False Claims Act Claim pursuant to 31 U.S.C. § 3729 et seq.

Intentionally Presenting Claims for Payment to the United States for Schedule II Narcotics Which Were Dispensed as a Sec. 290.10 Emergency When PharMerica Knew There Was No Emergency or Had No Reason to Believe There Was an Emergency.

38. Relator reasserts and incorporates by reference all paragraphs set forth above as if restated herein.

39. On information and belief, for at least two years prior to Relator commencing employment with PharMerica facilities corporate-wide regularly dispensed and billed to the United States Schedule II-V controlled substances without a prescription in response to phone orders and faxed discharge orders and physician orders despite an absence of any type of emergency, any claimed emergency, or any documented emergency.

40. Except as set forth below, PharMerica made no follow-up to such non-prescription orders to obtain prescriptions and/or physician signatures.

41. PharMerica regularly fills such orders, which are treated as “Emergency Dispense” (“ED”), with a 3-day supply of the controlled substance and re-fills them three to four times without regard to whether a signed prescription has been received. On information and belief, no corporate procedure provided to facilities prevents such practice.

42. A pharmacist is prohibited from dispensing a Schedule II controlled narcotic substance without a written prescription signed by a physician. 21 C.F.R. §1306.11(a). The only exception to this regulatory prohibition is in an “emergency situation” whereby a pharmacist may dispense a Schedule II controlled narcotic substance upon receiving oral authorization from the prescribing physician, provided that: (1) the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period; (2) the prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required in 21

C.F.R. §1306.05, except for the signature of the prescribing physician; (3) if the prescribing physician is not known to the pharmacist, he or she must make a reasonable effort to determine that the oral authorization came from a registered physician; and (4) within seven (7) days after authorizing an emergency oral prescription, the prescribing physician shall provide a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. 21 C.F.R. §1306.11(d).

43. 21 C.F.R. §290.10 defines an emergency situation. §290.10(b) specifically states that an emergency situation would not include a situation “where an appropriate alternative is available, including administration of a drug which is not a controlled substance under Schedule II of the Act”. The narcotic boxes that PharMerica provides SNFs have Schedule II-V substances, and the schedule III-V should be used in emergency situations. Because PharMerica is responsible for the drugs in the narcotic boxes they are also responsible for making it clear that Schedule II narcotics should not be taken from the narcotic box unless there is no appropriate alternative treatment available from the narcotic box. By not effectively supervising access and use of narcotic boxes PharMerica is falling short of their responsibility and permitting the overuse of costly Schedule II medications when less expensive and more appropriate Schedule III-V medications are available. The following are examples of times that Medicare was billed for the more costly Schedule II narcotic when less expensive, and more appropriate emergency medications were available:

- a. Medicare was billed \$27.37 for Fentanyl 12 Mcg/Hr patch that was dispensed to patient D.M. on June 20, 2009 at the South Shore facility when other appropriate alternative treatment was available.

- b. Medicare was billed \$31.93 for Oxycontin 20mg that was dispensed to patient N.W. on May 31, 2009 at the Golden Living Sheboygan facility when other appropriate alternative treatment was available.
- c. Medicare was billed \$50.42 for Fentanyl 50mcg/hr patch that was dispensed to patient P.H. on June 4, 2009 at the Golden Living Silver Spring facility when other appropriate alternative treatment was available.
- d. Medicare was billed \$51.29 for Fentanyl 100 mcg/hr patch that was dispensed to patient R.G. on June 13, 2009 at the Golden Living South Shore facility when other appropriate alternative treatment was available.
- e. Medicare was billed \$28.71 for Oxycontin 10mg that was dispensed to patient J.N. on June 18-21 at the Door County Memorial Hospital SNF when other appropriate alternative treatment was available.

44. Relator has personal knowledge that PharMerica's Pewaukee, Wisconsin facility violates 21 C.F.R. §1306.11(a) by regularly dispensing Schedule II narcotics without obtaining written prescriptions more than 90% of the time. Relator has personal knowledge that PharMerica's Pewaukee, Wisconsin facility does not document or attempt to ascertain whether an emergency situation exists before dispensing Schedule II narcotics without a written prescription. By failing to verify that an emergency situation does exist, PharMerica's disbursement of Schedule II narcotics without a signed prescription violates 21 C.F.R. §1306.11(a).

45. Pharmacists are required to notify the nearest office of the United States Food and Drug Administration ("FDA") if the prescribing physician fails to deliver a written prescription within the seven-day timeframe; failure of the pharmacist to do so voids the authority of the

pharmacist to dispense the Schedule II controlled narcotic substances without a written prescription of a prescribing physician and denies PharMerica the opportunity to submit an invoice for such controlled substances to the United States for payment because the substances were illegally dispensed. 21 C.F.R. §1306.11(d)(4).

46. Relator has personal knowledge that PharMerica's Pewaukee, Wisconsin facility violated 21 C.F.R. § 1306.11.(d)(4) by regularly dispensing emergency prescriptions without obtaining an oral prescription from a prescribing physician. Instead of obtaining an oral prescription, PharMerica uses old prescriptions and order forms to generate the necessary information to process, bill for, and dispense the emergency prescription. As an example:

- a. Medicare was billed by PharMerica for the medication for patient J.E. without obtaining a written or oral prescription from the physician. On June 14, 2009 PharMerica dispensed Fentanyl 50mcg (a Schedule II controlled narcotic substance) to an SNF for patient J.E. based on old order forms, and without a valid prescription.
- b. Medicare was billed by PharMerica for the medication for patient J.E. without obtaining a written or oral prescription from the physician. On May 16, 2009 PharMerica dispensed Oxycontin 40mg (a Schedule II controlled narcotic substance) to an SNF for patient J.E. based on old order forms, and without a valid prescription.

47. The United States of America has been damaged by all of the aforementioned misrepresentations and failures to comply with requisite agreements and regulations in an as of yet undetermined amount. With respect to the aforementioned misrepresentations and failures to comply, PharMerica knowingly made false claims to officials of the United States for the purpose of obtaining compensation.

48. On information and belief, PharMerica's other facilities also follow the same practices of intentional non-compliance and false billing. On information and belief, PharMerica's corporate offices are aware of the non-compliant practices and have not taken action to accomplish compliance which would substantially reduce corporate profits.

V. Count II. Federal False Claims Act Claim pursuant to 31 U.S.C. § 3729 et seq.

Intentionally Presenting Claims for Payment to the United States for Schedule II Narcotics

Which Were Dispensed As A Sec. 290.10 Emergency Without A Signed Prescription Within

Seven Days

49. Relator reasserts and incorporates by reference all paragraphs set forth above as if restated herein.

50. PharMerica's Pewaukee, Wisconsin facility regularly did not obtain or attempt to obtain physician signatures within the required seven-day timeframe for controlled substances dispensed in emergency situations and PharMerica knowingly submitted claims for payment of such dispensed controlled drugs, including the following specific examples:

a. Patient H.N. residing at the Three Oaks facility was dispensed Oxycontin 10mg on June 5, 2009. Oxycontin is a Schedule II controlled narcotic as defined in 21 C.F.R. §1308.12(b)(1)(xiif). PharMerica billed the United States through its Medicare program for the said controlled drugs on or around the same date. As of June 30, 2009 no physician's signature was obtained for the prescription, in violation of the seven day requirement of 21 C.F.R. §1306.11(d).

b. Patient N.B. residing at the Mt. Carmel Milwaukee facility was dispensed Endocet 5-325 on June 3, 2009. Endocet 5-325 is a Schedule II controlled narcotic as defined in 21 C.F.R. §1308.12(b)(1)(xiii). PharMerica billed

the United States through its Medicare program for the said controlled drugs on or around the same date. As of June 17, 2009 no physician's signature was obtained for the prescription in violation of the seven day requirement of 21 C.F.R. §1306.11(d).

- c. Patient M.K. residing at the KPS Wausau facility was dispensed Fentanyl 12mcg on June 5, 2009. Fentanyl is a Schedule II controlled narcotic as defined in 21 C.F.R. §1308.12(c)(9). PharMerica billed the United States through its Medicare program for the said controlled drugs on or around the same date. As of June 17, 2009 no physician's signature was obtained for the prescription in violation of the seven day requirement of 21 C.F.R. §1306.11(d).
- d. Patient J.C.M. residing at the KPS- Woodstock facility was dispensed Endocet 5-325 on May 27, 2009. Endocet 5-325 is a Schedule II controlled narcotic as defined in 21 C.F.R. §1308.12(b)(1)(xiii). PharMerica billed the United States through its Medicare program for the said controlled drugs on or around the same date. As of June 17, 2009 no physician's signature was obtained for the prescription in violation of the seven day requirement of 21 C.F.R. §1306.11(d).
- e. Patient A.T. residing at the Colonial Manor Milwaukee facility was dispensed Oxycontin 20mg on March 5, 2009. Oxycontin is a Schedule II controlled narcotic as defined in 21 C.F.R. §1308.12(b)(1)(xiii). PharMerica billed the United States through its Medicare program for the said controlled drugs on or around the same date. As of June 2, 2009 no

physician's signature was obtained for the prescription in violation of the seven day requirement of 21 C.F.R. §1306.11(d).

- f. Patient J.B. residing at the Colonial Manor Milwaukee facility was dispensed Fentanyl 25mcg on March 5, 2009. Fentanyl is a Schedule II controlled narcotic as defined in 21 C.F.R. §1308.12(c)(9). PharMerica billed the United States through its Medicare program for the said controlled drugs on or around the same date. As of June 2, 2009 no physician's signature was obtained for the prescription in violation of the seven day requirement of 21 C.F.R. §1306.11(d).
- g. Patient W.M. residing at the Colonial Manor Milwaukee facility was dispensed Oxycodone HCL 5mg on March 6, 2009. Oxycodone is a Schedule II controlled narcotic as defined in 21 C.F.R. §1308.12(b)(1)(xiii). PharMerica billed the United States through its Medicare program for the said controlled drugs on or around the same date. As of June 2, 2009 no physician's signature was obtained for the prescription in violation of the seven day requirement of 21 C.F.R. §1306.11(d).

51. PharMerica was aware of the requirement to obtain the prescribing physician's signature within seven-days after the emergency prescription, yet Defendant knowingly submitted false claims for payment without having obtained or attempting to obtain the requisite signature within the allowable timeframe and without notifying the proper authorities. By failing to comply with the requirements of 21 C.F.R. §1306.11(d)(4) PharMerica did not have the authority to dispense controlled narcotic medications or to bill the United States Government for such dispensed controlled substances.

52. On information and belief, for at least two years prior to Relator's hire with PharMerica and during her employment before Relator complained about the above non-compliance, Defendant took no measures and provided no staff to follow-up to obtain signed prescriptions for dispensed Schedule II controlled substances.

53. On information and belief, PharMerica's other facilities also follow the same practices of intentional non-compliance and false billing. On information and belief, PharMerica's corporate offices are aware of the non-compliant practices and have not taken action to accomplish compliance which would substantially reduce corporate profits.

54. On May 18, 2009, Defendant's corporate office sent a memo to the facilities it has under contract, stating that effective immediately, in order to qualify for the emergency exception so that a signed prescription is not required before dispensing controlled substances, the patient must be either a new admission or the drug order must be must be a new order for the controlled substance. Prior to that time policy required no basis for the emergency exception. PharMerica new May 18, 2009 policy remains out of compliance and continue the policy and practice of submitting false claims for payment to the United States.

55. On information and belief, PharMerica has scores of boxes of orders for controlled substances, which has been dispensed and billed to the United States but for which PharMerica has not obtained and not attempted to obtain signed physician prescriptions within the 7-day time frame or at all.

56. On June 16, 2009 Related learned of and viewed in the PharMerica Pewaukee facility's "Harry Potter" room, boxes of unsigned prescriptions and orders that had been billed to the United States and which management had intentionally hid as a result of non-compliance. These boxes were approximately the standard sized banker's boxes which are 10"H x 12"W x 24"D. A similar sized printer paper box stores 3000 neatly packed sheets of individual paper.

Upon information and belief, each banker's box contains approximately 2000-3000 unsigned and illegally billed prescriptions or orders in violation of 21 C.F.R. §§ 1306.11(a) and (d)(4). Relator pulled random samples of the unsigned orders for prescription medications and checked their billing history in the PharMerica AS400 system. Relator found, for example:

- a. PharMerica billed Medicare and Wisconsin Medicaid for Colonial Manor patient, R.L., who was given two separate doses of Fentanyl (one 25 mcg, the other 50 mcg) without a signed prescription within seven days, a violation of 21 C.F.R. § 1306.11(d)(4). The medication was dispensed on July 3, 2007 but the signature from the doctor was still missing as of June 16, 2009 when Relator discovered the prescription document.
- b. PharMerica billed Michigan Medicaid for MaryHill Manor patient, I.W., who was given Fentanyl 25 mcg on April 3, 2007. The prescription was still unsigned when Relator discovered it on June 16, 2009.

57. Relator has personal knowledge that PharMerica's practice of billing the United States Government for dispensed controlled narcotic medications without a valid prescription occurs at other PharMerica locations. In an email dated November 3, 2008 from PharMerica Director of Corporate Compliance/Regulatory Affairs, Sharon Hartman that was sent to Jay Palin, Vice President of Operations, and Robert Nolan, Vice President & Chief Compliance Officer, and subsequently forwarded to Relator, Hartman states that there were outstanding billed Schedule II controlled narcotic substance prescriptions unsigned after seven (7) days at the following PharMerica locations: 989 in Warren, MI, 236 in Fridley, MN, 81 in Worthington, OH 104 in Nashville, TN, and 171 in Pewaukee, WI. The e-mail was forwarded to all PharMerica General Managers, including Maupin who forwarded it to Relator to have her conduct the research into the outstanding prescriptions for the Pewaukee, Wisconsin PharMerica. The total amount of current

billed and unsigned prescriptions from those five locations at that time was in excess of sixteen hundred (1600) not including the older boxed billed and unsigned prescriptions, which dated back to at least the beginning of 2007. PharMerica intentionally billed the United States Government for the invalid prescriptions which, due to violations of 21 C.F.R. §1306.11(d)(4) never were eligible for reimbursement.

58. Relator has personally viewed prescriptions that remain unsigned, but were filled and billed as far back as April 3, 2007. Defendant was aware no later than November 3, 2008 that it was in violation of regulations regarding billed Schedule II controlled narcotic substance prescriptions unsigned after seven days. At least as early as November 3, 2008 Defendant requested from several of its locations their status on the number of billed schedule II controlled narcotic prescriptions unsigned after seven days. Upon information and belief, Defendant continued to monitor the number of billed schedule II controlled narcotic prescriptions unsigned after seven days but took no action to prevent billing for the non-compliant prescriptions.

59. In an e-mail dated April 1, 2009 sent on behalf of Palin from Karanne Isler, administrative assistant to Palin, to all the PharMerica general managers, Palin states that recovery of the unsigned outstanding prescriptions is a priority that needs attention. Maupin forwarded this e-mail to Relator to have Relator do the weekly report on the outstanding prescriptions. Some of these prescriptions had been outstanding from 2008. At the request of Maupin, Relator began contacting physicians to get them to sign the prescriptions; despite the fact that the prescriptions would still have been invalid at the time of billing because they had not been signed within the seven day period. Maupin had instructed Relator to get the signatures anyway and in e-mail dated April 2, 2009 states, "I know it's not exactly a signed script, but it's better than nothing and *might* be somewhat of a defense if we were to be unfortunate enough to get audited."

60. In an e-mail dated April 20, 2009 Relator informed Maupin that employees in the Data Entry division of PharMerica Pewaukee, Wisconsin were not complying with assisting in the recovery of outstanding prescriptions, as was ordered in the April 1, 2009 e-mail. On information and belief, Maupin did nothing in response to this e-mail.

61. On a regular basis, PharMerica's SNF customers dispense Schedule II controlled narcotic substances to a patient prior to PharMerica's receipt of a valid prescription. As representative examples, the patients listed in paragraph 50 above all received their medications from a narcotic box prior to receipt by PharMerica of a valid prescription. PharMerica routinely bills the United States Government for the Schedule II controlled narcotic substances dispensed without a prescription.

62. The United States of America has been damaged by all of the aforementioned misrepresentations and failures to comply with requisite agreements and regulations in an as of yet undetermined amount. With respect to the aforementioned misrepresentations and failures to comply, PharMerica knowingly made false claims to officials of the United States for the purpose of obtaining compensation.

63. On information and belief, PharMerica's other facilities also follow the same practices of intentional non-compliance and false billing. On information and belief, PharMerica's corporate offices are aware of the non-compliant practices and have not taken action to accomplish compliance which would substantially reduce corporate profits.

V. Count III Federal False Claims Act Claim pursuant to 31 U.S.C. § 3729 et seq.

Intentionally Presenting Claims for Payment to Defendant for Schedule III, IV and V

Narcotics Sales which were Dispensed in Violation of the Law.

64. Relator reasserts and incorporates by reference all paragraphs set forth above as if restated herein.

65. A pharmacist may dispense directly schedule III, IV, or V controlled narcotic substances, pursuant to either a written prescription signed by a physician or a facsimile of a written, signed prescription transmitted by the physician or the physician's agent to the pharmacy. Additionally, a pharmacist may dispense directly schedule III, IV, or V controlled narcotic substances pursuant to an oral prescription made by a physician and promptly reduced to writing by the pharmacist as long as it contains all information required in §1306.05, except for the signature of the physician. 21 C.F.R. §1306.21(a) Pursuant to the Federal Food, Drug, and Cosmetic Act 21 U.S.C. §301 *et seq.* scheduled controlled narcotic substances may only be dispensed upon a written prescription of a practitioner licensed by law to administer such drug, or upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. A physician's order does not qualify as a valid prescription pursuant to 21 C.F.R. § 1306.05(a) as it does not contain the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner.

66. Relator has personal knowledge that PharMerica routinely dispenses Schedule III, IV and V controlled narcotic substances and bills the United States government for those medications based solely on physician's orders which do not comply with the requirements of 21 C.F.R. §1306.05(a) and without obtaining a valid prescription. For instance, Medicare was billed for the Schedule III controlled narcotic substance Hydrocodone 5-325, 5-500, 10-325 for the following three patients based solely on a physician's order: (a) patient I.K. at the Mt. Carmel Milwaukee facility on June 16, 2009; (b) patient D.K. at the Beaver Dam facility on June 9, 2009, and (c) patient L.J at the Wisconsin Dells facility on June 12, 2009.

67. The United States has been damaged by all of the aforementioned misrepresentations and failures to comply with requisite agreements and regulations in an as of yet undetermined amount. With respect to the aforementioned misrepresentations and failures to comply, PharMerica knowingly made false claims to officials of the United States for the purpose of obtaining compensation.

68. On information and belief, PharMerica's other facilities also follow the same practices of intentional non-compliance and false billing. On information and belief, PharMerica's corporate offices are aware of the non-compliant practices and have not taken action to accomplish compliance which would substantially reduce corporate profits.

VI. Count IV Federal False Claims Act Claim pursuant to 31 U.S.C. § 3729 et seq.

**Failure to Credit Payments Made by the U.S. Government for Returned Medications and
Double Billing for Returned Medications**

69. Relator reasserts and incorporates by reference all paragraphs set forth above as if restated herein.

70. Relator has personal knowledge of Defendant's practice of failing to give credit for medications that have been returned after they have been billed to the United States Government and Defendant's practice of billing the United States Government more than once for these same medications.

71. On information and belief, PharMerica's other facilities also follow the same practices of intentional failure to credit and double billing. On information and belief, PharMerica's corporate offices are aware of these practices and have not taken action to accomplish compliance which would substantially reduce corporate profits.

72. Relator has personal knowledge that labels are created for drugs that are billed and submitted to the United States for payment. When medication is returned to PharMerica because

the patient is discharged or deceased, or the medication is discontinued, for example, technicians receive the returned medications and peel the label off of the package and put the label on a "Prescriptions for Credit" sheet. Then the technicians place the unlabeled package back on the shelf inventory and PharMerica follows the practice of not crediting the United States for the returned medications. Relator personally accessed the billing data in PharMerica's AS400 system and observed that no credits had been made as of July 1, 2009 for all of the following examples. The United States was billed for the following patients and drugs, that were subsequently returned to the PharMerica inventory (shelves) to be re-dispensed and re-billed at a later date without being credited to the United States:

- a. Patient C.J. at the Woodstock facility was sent Schedule II narcotic controlled substance Oxycodone on June 22, 2009 that was subsequently returned but not credited;
- b. Patient C.B. at the Dorchester facility was sent Schedule II narcotic controlled substance Fentanyl on June 12, 2009 that was subsequently returned but not credited;
- c. Patient I.B. at the Three Oaks facility was sent Schedule II narcotic controlled substance Morphine Sulfate on June 15, 2009 that was subsequently returned but not credited;
- d. Patient R.G. at the Silver Spring facility was sent Schedule II narcotic controlled substance Endocet on June 13, 2009 that was subsequently returned but not credited.

73. Medications billed to the United States government and sent to Defendant's customers are regularly packaged in blister pack cards, which are known in the industry as "Bingo Cards." These cards are used so that one dosage may be handled without the other dosages

becoming contaminated. Each card contains a fixed supply of medications, usually a weekly or monthly amount. PharMerica staff either creates cards from bulk medications, or the cards arrive at PharMerica already packaged by the pharmaceutical company. Entire cards are then billed, shipped to PharMerica's customers and dispensed to individual patients.

74. Defendant's SNF customers regularly return unused or partially used "Bingo Cards" to PharMerica if a patient is no longer under the SNF customer's care or if the patient is dead, for example. When "Bingo Cards" containing medications which have been billed to the United States are returned to PharMerica the United States is not credited the unused amount. Instead a) the card is destroyed with no credit given; b) the unused medication from a partially used card is taken to fill a different order for which the United States government is again billed for the same medication; or c) whole unused cards are relabeled and again billed to the United States government for a new patient. For an example patients C.J. and R.G. above were sent their medications in "Bingo Cards" that were subsequently returned.

75. Relator has personal knowledge that PharMerica regularly bills the government for prescriptions that are sent to deceased patients. A November 9, 2008 e-mail sent to Relator from Lisa Oare-Shanks, PharMerica's Vice President of National Accounts, notes that Defendant continues to send medications to its SNF customers which are designated for patients who are deceased. Upon information and belief, these medications sent to dead patients are billed to the United States government.

76. The United States of America has been damaged by all of the aforementioned misrepresentations and failures to comply with requisite agreements and regulations in an as of yet undetermined amount. With respect to the aforementioned misrepresentations and failures to comply, PharMerica knowingly made false claims to officials of the United States for the purpose of obtaining compensation.

77. On information and belief, PharMerica's other facilities also follow the same practices of intentional non-compliance and false billing. On information and belief, PharMerica's corporate offices are aware of the non-compliant practices and have not taken action to accomplish compliance which would substantially reduce corporate profits.

VII. Count V Federal False Claims Act Claim pursuant to 31 U.S.C. § 3729 et seq.

Submitting Claims to the U.S. Government for Individuals who do not Have Prescriptions for the Medications Billed and Submitting Claims for one Type of Medication and Providing a Different Type

78. Relator reasserts and incorporates by reference all paragraphs set forth above as if restated herein.

79. Relator has personal knowledge of Defendant's practice of billing the United States Government for medications dispensed to individuals who do not have a prescription for the medications that were dispensed. As the Pharmacy Operations Manager, Relator has access to and creates Pharmacy Dispensing Occurrences (PDOs) into the PharMerica intranet.

80. As a representative example the following PDOs detail how PharMerica bills the United States for medications the respective patients did not receive:

- a. On March 2, 2009 PharMerica billed the United States for Seroquel 50mg on behalf of a Sheridan facility patient K.D., who had no such prescription;
- b. On February 1, 2008 PharMerica billed the United States for Coumadin on behalf of a Mt. Carmel Burlington facility patient S. D., who had no such prescription;
- c. On December 8, 2008 PharMerica billed the United States for Alprazolam .25 mg on behalf of a Mt. Carmel Milwaukee patient J.D. However, the

medication was dispensed to fill the prescription of another patient, D.N., who was a Medicare patient covered by a different Medicare plan;

- d. On April 14, 2009 PharMerica billed the United States for Methylin 10 mg on behalf of a Mt. Carmel Milwaukee patient V.K. yet the medicine was delivered to N.H., a non-Medicare patient.

81. Relator has personal knowledge that PharMerica submitted claims for payment for one type of medication and then provided a different type of medication to the customer. By reviewing and submitting PDOs, Relator has access and first-hand knowledge of patients that had prescriptions for one medication but were given another.

82. As a representative example, the following individuals were provided a different type of medication than what was billed:

- a. On February 10, 2009 PharMerica billed the United States on behalf of Eastview facility patient B.D. for Actos 30mg; however, B.D. was provided with Ciprofloxacin 500mg;
- b. On March 3, 2009 PharMerica billed the United States on behalf of Mt. Carmel Milwaukee patient D.N. for Flagyl 500mg; however, D.N. was provided with Metformin 500mg;
- c. On February 10, 2009 PharMerica billed the United States on behalf of Northridge patient H.S. for Avapro 150mg; however, H.S. was provided with Calcitriol .25mg.

83. The United States of America has been damaged by all of the aforementioned misrepresentations and failures to comply with requisite agreements and regulations in an as of yet undetermined amount. With respect to the aforementioned misrepresentations and failures to

comply, PharMerica knowingly made false claims to officials of the United States for the purpose of obtaining compensation.

84. On information and belief, PharMerica's other facilities also follow the same practices of intentional non-compliance and false billing. On information and belief, PharMerica's corporate offices are aware of the non-compliant practices and have not taken action to accomplish compliance which would substantially reduce corporate profits.

PRAYER FOR RELIEF

WHEREFORE, the United States is entitled to damages from PharMerica Corporation in accordance with the provisions of 31 U.S.C. §§ 3729-3733, and Plaintiff/Relator requests that judgment be entered against Defendant, ordering that:

- a. Defendant cease and desist from violating the False Claims Act, 31 U.S.C. § 3729 *et seq.*;
- b. Defendant pays an amount equal to three times the amount of damages the United States has sustained because of Defendant's actions, plus a civil penalty against Defendant of not less than \$5,000 and not more than \$11,000 for each violation of 31 U.S.C. § 3729;
- c. Plaintiff/Relator be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);
- d. Plaintiff/Relator be awarded all costs of this action, including attorneys' fees, expenses, and costs pursuant to 31 U.S.C. § 3730(d);
- e. The United States and Plaintiff/Relator be granted all such other relief as the Court deems just and proper.

PLEASE TAKE NOTICE THAT THE PLAINTIFF DEMANDS THE ABOVE ENTITLED ACTION TO BE TRIED TO A 12 PERSON JURY.

Respectfully submitted and dated this 2nd day of July 2009.

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